

2005年09月15日 (木) 10:51

株式会社ノバライスシステム研究所

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DECLARATION OF YOSHIKAZU TOBINAGA

I, Yoshikazu Tobinaga, am one of the inventors of U.S. Patent Application No. 10/666,581 and do hereby declare as follows:

1. A summary of my professional background is attached as Exhibit A.
2. I have read U.S. Patent Application Publication No. US 2004/0010237, hereinafter called D'Ussel, and understand it.
3. D'Ussel discloses a needle made of metal, such as aluminum, not sugar. There is no disclosure of the needle being a microneedle, rather the disclosure relates to a needle that is not indicated to be anything other than a standard size needle. D'Ussel discloses a tip formed on the end of the metal needle by immersing in hot material, such as a sugar or a salt.
4. There is no disclosure of the immersing being capable of forming discrete individual tips on the ends of a plurality of microneedles simultaneously immersed in a hot sugar bath.
5. There is no teaching in D'Ussel of needles made of sugar. It only discloses adding a tip of sugar to an existing metal needle structure.
6. According to D'Ussel there must be some basic needle structure so that when it is immersed a sugar tip will be formed. Thus D'Ussel would not teach or suggest forming needles of sugar.
7. Furthermore, D'Ussel discloses sterilization of the needle, but sugars, such as maltose, disintegrate at temperatures of sterilization. Thus the disclosure of D'Ussel is inoperative.

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8. For these reasons, it is my belief that one of ordinary skill in the art would not be taught to make microneedles of sugar, but would disregard D'Ussel as inoperative when considered in relation to microneedles.

Respectfully submitted,

Y. Tobinaga
Yoshikazu Tobinaga
CEO of Nano Device and
System Research, Inc.,
Kyoto Japan
August 26, 2005

EDUCATION & BUSINESS CAREER**Yoshikazu Tobinaga**

COO, President, Nano Device and System Research, Inc.

1. EDUCATION**Electro-communication University (1969-1973)**

DIVISION: Electro-communication and Material Science

SUBJECT: - Physics (Quantum Mechanics and Electromagnetism)

- Electro communication (Communication theory, Information theory)
- Material Science (Semiconductor theory and chemical analysis)

Graduation thesis: Dye laser research in the Electronics Technology Laboratories (ETL) of the Minister of International Trade and Industries.**2. BUSINESS****2.1 NIPPON ELECTRIC COMPNY (NEC): 1973-1977**

- 1973-1977: ULSI section in the Tamagawa Semiconductor Division
- 1977-1981: The central Research Laboratory
- Design and Production of High Frequency MOSFET
- Fine Lithography in IC process
- Development and production of Multilayer Electrode in IC
- Development of GaAs MESFET
- Design and production of Custom LSI
- Development of DSP-LSI
- 1/f noise Research

2.2 IBM: 1981-1985**Assignment: East Fishkill Laboratory joining the Watson Research Lab program.**

- Development of Electron beam lithography
- Development and production of sub micron meter Ground Rule microprocessor
- Research on X-ray lithography via synchrotron Radiation for fine process
- Research of FRACTAL and 1/f noise
- Laboratory Establishment for Yasu of IBM Japan
- Research of nonlinear mathematics based on Markov chain

EXHIBIT A

2.2 SUMITOMO METAL INDUSTRIES TECHINCAL LAB.:1985-1995

- Development and production of Dry process on Electron Cyclotron Resonance (ECR) Plasma Research
- ASIC design and production line establishment
- Research of Neural processing and device
- Research of Nonlinear Mathematics like Chaos and Fractals
- Development and production of bio-sensor as ASIC application
- Research of brain function measurement by multi-channel SQUID
- Research of inverse problem in Mathematics for cortical function analysis
- Research of high temperature super conducting on SQUID development
- Physiological research and regulation of brain-function measurement: Epilepsy Patients in the Medical Division of Tokyo University

2.3 SUMITOMO PRECISION PRODUCTION Co. Ltd.: 1995-1997

Dispatch from SUMITOMO METAL INDUSTRIES TECHINCAL LAB

- Dry Process Business set up for Micro Machine technology jointing English company, Surface Technologies System (STS)
- Research of Micro Reactor for protein structure analysis via synchrotron

2.4 Kansai Research Institute (Branch of Stanford Research Institute, before) : 1997-2001

- Research of Brain Activity by SQUID
- Research of 3D display joining Carnegie Melon University
- Micro Machine Device Development for Micro Pump
- Research of DNA chip process and bio informatics via data mining
- Research of nonlinear Mathematics for data mining

2.5 Nano Device and System Research, Inc. (Nanodes) : 2001-2005 (now)

Company Establishment of Nanodes in April second, 2001

- Nano Gap DNA chip without PCR
- Research of brain function measurement of normal person titled "leaning and brain activity in the complexity" with the economics research of Kyoto Univ.
- X ray lithography by synchrotron Radiation for device processing
- Drug Delivery System, micro needle, for Dermatological applications

EXHIBIT A

3. SOCIET ACTIVITIES AND PRESENTAIONS

- Japan Physical Society
- Japan Application Physics Society
- Japan Medical Engineering Society
- Japan Neurology Society
- Japan Biology Society
- IBM Inside Symposium
- 1/f Noise Symposium
- IEEE Medical Engineering
- IEEE Computer
- Micro electronic device
- New York Academy of Science
- SPIE
- Society of Nonlinear Mathematics
- Vacuum Science

EXHIBIT A